510K(k) SUMMARY

SUBMITTER:	**Gambro Renal Products** **10810 West Collins Avenue** **Lakewood, CO 80215** **(303) 231-5075**
DATE PREPARED:	**September 15th, 2002**
DEVICE NAME:	**Gambro POLYFLUX 6 LR, 8 LR, and 10 LR Capillary Dialyzer/Filter Labeled for Single & Multiple Use**
CLASSIFICATION NAMES:	**Hemodialyzer**
PREDICATE DEVICE:	**Gambro POLYFLUX 6L, 8L, & 10L Capillary Dialyzers / Filters**

MAY 0 6 2003

Device Description:

The Gambro POLYFLUX 6 LR, 8 LR, and 10 LR, Capillary Dialyzers labeled for multiple use / reuse are identical in design, materials, function and intended use to the Gambro POLYFLUX 6L, 8L, and 10L Capillary Dialyzers/ Filters labeled for single use which have been previously cleared by the FDA under a 510(k) Notification for single use (510(k) Notification K010985).

These devices are intended for use in hemodialysis for the treatment of acute and chronic renal failure and for certain types of intoxications. They may also be used in cases of acute fluid overload for the removal of plasma water. The membrane used in this device is polyarylethersulfone (PES) which is identical to the membrane utilized in the Gambro POLYFLUX 6L, 8L, and 10L Capillary Dialyzers/ Filters labeled for single use which have been previously cleared for marketing in the United States under 510K Notifications (K010985).

Blood enters a blood inlet port where it is distributed to the hollow fibers. Each hollow fiber has an inner diameter of approximately 215 microns (wet hollow fiber internal diameter) and a wall thickness of 50 microns. The number of hollow fibers in each hemodialyzer / filter is 10,00 for the POLYFLUX 6 LR, 10,000 for the POLYFLUX 8 LR, and 12,500 for the POLYFLUX 10 LR. This effective membrane length is 210 mm for the POLYFLUX 6 LR, and 250 mm for the POLYFLUX 8 LR and 10 LR. The effective membrane surface area is 1.4 square meters for the POLYFLUX 6 LR, 1.7 square meters for the 8 LR and 2.1 square meters for the 10 LR. The housing and end caps of this hemodialyzer / filter are made of polycarbonate. The fibers used in the Gambro POLYFLUX 6 LR, 8 LR, and 10 LR are of the same composition as those

previously approved for the Gambro POLYFLUX L 6L, 8L, and 10L Capillary Dialyzers/ Filters labeled for single use and multiple use (K010985). The patient's blood traverses the inside of the hollow fibers and exits the device via a blood exit port.

By means of a hydrostatic pressure or transmembrane pressure which is created by a combination of positive and negative pressures across the membrane, plasma water along with certain lower molecular weight solutes pass through the membrane and into the dialysate or filtrate compartment of the device. Removal of uremic toxins and waste products are removed from the patient's blood in this device by means of both diffusion and convection through the membrane and into the counter current flowing dialysis solution during hemodialysis. The dialysate exits the devices via a dialysate outlet port.

Predicate Devices:

The Gambro POLYFLUX 6LR, 8LR, and 10LR, Capillary Dialyzers labeled for multiple use, are identical in design, materials, intended use and construction to the currently marketed Gambro POLYFLUX 6L, 8L, and 10L, Capillary Dialyzers / Filters, labeled for single use. These dialyzers (POLYFLUX 6L, 8L, and 10L, Capillary Dialyzers / Filters) have been cleared for marketing / sale in the United States under 510K Notification K010985 for single use. Both the predicate and the proposed devices, incorporate identical membranes and other blood and non-blood contact materials and have identical performance characteristics. They are substantially equivalent to the listed predicate devices. The intended use for the proposed and predicate devices is also the same, hemodialyzer/ filter with the exception of single versus multiple use which has been added to the POLYFLUX LR.

PREDICATE DEVICES

DEVICE NAMES	Gambro POLYFLUX 6L, 8L & 10L Capillary Dialyzer/ Filter
INTENDED USE	Hemodialyzer/Filter
510K NUMBER	K010885
APPROVAL DATE	10/10/01

With respect to performance, these hemodialyzer/filters perform in a manner substantially equivalent to each other. We therefore consider the proposed devices substantially equivalent to existing predicate devices in commercial distribution in the United States.

Intended Use:

POLYFLUX LR Indications:

POLYFLUX LR is intended for use in hemodialysis for the treatment of acute and chronic renal failure.

The POLYFLUX LR may be reprocessed for reuse on the same patient.

This indication statement is essentially the same as the indication statement for the predicate devices.

Technological Characteristics:

Comparing the proposed devices to the predicate devices, they are substantially equivalent to the predicate devices. Both the proposed and predicate devices use the same hollow fiber membrane and other blood and non-blood contact materials. Both the proposed and predicate devices use polycarbonate for the housing and header material and polyurethane for the membrane potting material and are steam sterilized.

Summary of Non-Clinical Tests:

In vitro data was collected according to the FDA Guidance for Hemodialyzer Reuse Labeling.

Clinical Test Results:

Clinical data was collected according to the FDA Guidance for Hemodialyzer Reuse Labeling.

Conclusions:

Testing performed on the Gambro POLYFLUX LR Capillary Dialyzers indicates that they are safe, effective, and perform as well as the predicate devices, when used in accordance with the instructions for use. In vitro and clinical performance data and directions for reuse have been included in the labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 6 2003

Jeffrey R. Shideman, Ph.D.
Director, Therapy Group Americas
Gambro Corporate Research
Gambro® Renal Products
10810 West Collins Avenue
LAKEWOOD CO 80215

Re: K023615
Trade/Device Name: POLYFLUX 6LR, 8LR, & 10LR Capillary Dialyzers/Filters labeled for Multiple/Re-Use
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 MSF
Dated: February 4, 2003
Received: February 5, 2003

Dear Dr. Shideman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) NUMBER (IF *KNOWN*): ~~*Not yet assigned*~~ K023615

DEVICE NAME: Gambro POLYFLUX 6 LR, 8 LR, and 10 LR Capillary Dialyzer/Filter Labeled for Single & Multiple Use

INDICATIONS FOR USE:

POLYFLUX LR Indications:

POLYFLUX LR is intended for use in hemodialysis for the treatment of acute and chronic renal failure.

The POLYFLUX LR may be reprocessed for reuse on the same patient.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation **(ODE)**

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023615